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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,761	07/24/2003	James P. Elia	1000-10-C2	1741

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,761

Applicant(s)

ELIA, JAMES P.

Examiner

Elizabeth C. Kemmerer, Ph.D.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/24/03, 6/16/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

Applicant's election of pancreas and cells in the reply filed on 16 June 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-33 are canceled. Claims 34-44 are under examination.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The newly submitted claims are directed to methods of treating a pancreas comprising local administration of cells at the pancreas, growing Islets of Langerhans, and restoring insulin production. The only section of the specification that mentions a pancreas is as follows (derived from the U.S. Patent Application Publication 20040071631:

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[0182] It may be desirable to restore a single function in a multifunctional organ. For example, a pancreas produces digestive enzymes and it produces insulin in the Islets of Langerhans. A practitioner may choose to stimulate only a desired portion. For example, inserting a gene for the creation of more Islets of Langerhans can be utilized to selectively restore an appropriate insulin production level without affecting the production of pancreatic digestive enzymes.

This paragraph is limited to methods of inserting a gene rather than to methods of administering cells.

Applicant points to several pages of the specification as support for the new claims (first paragraph of remarks section, amendment received 16 June 2006). All of these sections have been reviewed. However, only the above paragraph mentions a pancreas.

Claims 34-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure enables one skilled in the art to make and use the claimed invention in its full scope without resorting to undue experimentation include: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature or complexity of the invention; (5) the state of the prior art; (6)

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the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. See *In re Wands*, 8 USPQ2d. 1400 (Fed. Cir. 1988).

The quantity of experimentation required of the skilled artisan would be significant in view of the lack of direction/guidance presented by the specification, the absence of working examples, and the lack of information in the prior art regarding local administration of stem cells or germinal cells into a pancreas to grow Islets of Langerhans and restoring insulin production. The nature of the invention is highly complex, involving potential treatment of autoimmune diabetes, which has proven recalcitrant to cellular therapy despite decades of research. See Hussain et al. (2004, *Lancet* 364:203-205), who state:

Recently, Andreas Lechner and colleagues failed to see transdifferentiation into pancreatic beta cells after transplantation of bone-marrow cells into mice (*Diabetes* 2004; 53: 616-23). Last year, Jayaraj Rajagopal and colleagues failed to derive beta cells from embryonic stem cells (*Science* 2003; 299: 363). However, others have seen such effects. WHERE NEXT? As in every emerging field in biology, early reports seem confusing and conflicting. Embryonic and adult stem cells are potential sources for beta-cell replacement and merit further scientific investigation. Discrepancies between different results need to be reconciled. Fundamental processes in determining the differentiation pathways of stem cells remain to be elucidated, so that rigorous and reliable differentiation protocols can be established. Encouraging studies in rodent models may ultimately set the stage for large-animal studies and translational investigation.

Thus, it is clear that the state of the art in this approach was still considered complex and unpredictable even in 2004, after Applicant's filing date. Finally, the breadth of the claims encompasses administration of different types of stem cells, including germinal cells, bone marrow stem cells, and pluripotent stem cells.

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Due to the large quantity of experimentation necessary to determine how to treat a pancreas and grow islets of Langerhans and restore insulin production in a pancreas by administering stem cells, the lack of direction/guidance presented in the specification regarding how to achieve these results, the absence of working examples directed to the same, the complex nature of the invention, the contradictory state of the prior art (see Hussain et al., Lechner et al., and Rajagopal et al., cited above), the unpredictability of the process, and the breadth of the claims, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ECK



ELIZABETH KEMMERER
PRIMARY EXAMINER